

Claims

1. An oral solution comprising mitratapide or a pharmaceutically acceptable salt thereof, a pharmaceutically acceptable solvent wherein mitratapide has a solubility of 5 mg/ml or higher at a temperature of 22°C, a taste modifying agent and an antioxidant.  
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2. An oral solution as claimed in claim 1 wherein the pharmaceutically acceptable solvent is selected from the group consisting of dimethyl isosorbide, diethylene glycol monoethyl ether, caprylocaproyl macrogol-8 glyceride, propylene glycol monolaurate, polyethyleneglycol 200, 10 polyethyleneglycol 300 and polyethyleneglycol 400, and mixtures thereof, or mixtures of polyethylene glycols (PEGs ) having an average molecular weight higher than 400 with PEGs having an average molecular weight lower than 400 so that the mixture thereof is liquid at room temperature.  
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3. An oral solution as claimed in claim 2 wherein the pharmaceutically acceptable solvent is polyethyleneglycol 400.
4. An oral solution as claimed in any of claims 1 to 3 wherein the taste 20 modifying agent is an intense sweetener, a bulk sweetener, a flavouring agent, or a taste masking agent.
5. An oral solution as claimed in claim 4 wherein the taste modifying agent is an intense sweetener selected from the group consisting of saccharin, 25 aspartame, acesulfame, cyclamate, alitame, a dihydrochalcone sweetener, monellin, neohesperidin, neotame, stevioside or sucralose (4,1',6'-trichloro-4,1',6'-trideoxygalactosucrose), and the pharmaceutically acceptable salts thereof.
- 30 6. An oral solution as claimed in claim 5 wherein the intense sweetener is present in an amount ranging from 0.1 to 10 mg/ml.
7. A oral solution as claimed in claim 6 wherein the intense sweetener is sucralose.  
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8. An oral solution as claimed in any of claims 1 to 7 wherein the antioxidant is selected from the group consisting of BHA, BHT, propyl gallate, DL- $\alpha$ -tocopherol, and citric acid, and mixtures thereof.
- 5 9. An oral solution as claimed in claim 8 wherein the antioxidant is present in an amount ranging from 0.1 to 10 mg/ml.
- 10 10. An oral solution as claimed in claim 9 wherein the antioxidant is BHA.
- 10 11. An oral solution as claimed in claim 10 comprising 5 mg/ml mitratapide, sucralose in an amount ranging from 0.5 to 5 mg/ml, and BHA in an amount ranging from 1 mg/ml to 5 mg/ml, dissolved in PEG 400.
- 15 12. An oral solution as claimed in claim 11 comprising 5 mg/ml mitratapide, sucralose in an amount of 2 mg/ml, and BHA in an amount of 2 mg/ml, dissolved in PEG 400.
- 20 13. A process of preparing an oral solution as claimed in any of claims 1 to 12, characterized in that said process comprises the steps of dissolving mitratapide, the taste modifying agent and the antioxidant in the pharmaceutically acceptable solvent wherein mitratapide has a solubility of 5 mg/ml or higher at a temperature of 22°C, and stirring until a homogeneous solution is obtained.